

**Appendix 3-B (Risk Chapter)**  
**Human Health and Ecological Hazard Results**

Table 3-B.1 Health Hazard Results for Flexographic Ink Chemicals

Chemical name/ CAS number	Refer- ence*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity v alue**		Comment
					Systemic	Developmental	
Chemicals for which quantitative hazard data are available.							
Ammonia 7664-41-7	1, 2	dermal	ND	ND	74 mg/kg/day - L (bone effects) <sup>b</sup>	ND	The LOAEL is based on a study conducted on ammonia chloride.
		inhalation	sys: corneal, liver, respiratory, and spleen effects	0.1 mg/m <sup>3</sup> (skin and eye irritation, respiratory effects)	ND	ND	ND
		oral	sys: decreases in bone density, bone softening	ND	74 mg/kg/day - L (bone effects)	ND	The LOAEL is based on a study conducted on ammonia chloride.
Ammonium hydroxide 1336-21-6	2	dermal	ND	ND	1.8 mg/kg/day (W), 1.2 mg/kg/day (G) - N <sup>c</sup> (skin and eye irritation, respiratory effects)	ND	The NOAEL is based on an inhalation NOAEL of 6.4 mg/m <sup>3</sup> from a study conducted on ammonia.
		inhalation	sys: eye effects, nasal irritation, respiratory effects	0.1 mg/m <sup>3</sup> (skin and eye irritation, respiratory effects)	ND	ND	The RfC is based on a study conducted on ammonia.
		oral	ND	ND	1.8 mg/kg/day (W), 1.2 mg/kg/day (G) - ppm (skin and eye irritation, respiratory effects)	ND	The NOAEL is based on an inhalation NOAEL of 6.4 mg/m <sup>3</sup> from a study conducted on ammonia.
Barium 7440-39-3	2, 3	dermal	ND	0.007 mg/kg/day (increased blood pressure) <sup>b</sup>	ND	18 mg/kg/day - L (increased mortality, impaired liver function) <sup>b</sup>	ND
		inhalation	sys: decreased body weight, reproductive and respiratory effects, increased arterial blood pressure; dev: decreased survival and weight gain, changes in hematology parameters	ND	1.15 mg/m <sup>3</sup> - N (decreased body weight, increased arterial blood pressure, respiratory effects)	2.2 mg/m <sup>3</sup> - L (reduced survival, decreased weight gain, blood effects)	ND
		oral	sys: cardiovascular, kidney and reproductive effects, increased kidney weight, decreased survival; dev: increased mortality, impaired liver function	0.007 mg/kg/day (increased blood pressure)	ND	18 mg/kg/day - L (increased mortality, impaired liver function)	ND

Chemical name/ CAS number	Reference*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
2-Benzyl-2-(dimethylamino)-4'-morpholino-butyrophenone 119313-12-1	4	dermal	ND	ND	3000 mg/kg/day - L (neurotoxic effects) <sup>b</sup>	ND	ND
		inhalation	ND	ND	3000 mg/kg/day (10,500 mg/m <sup>3</sup> (W), 15,909 mg/m <sup>3</sup> (G)) - L (neurotoxic effects) <sup>b</sup>	ND	ND
		oral	sys: neurotoxic effects	ND	3000 mg/kg/day - L (neurotoxic effects)	ND	The systemic LOAEL is based upon a subacute study.
2-Butoxyethanol (glycol ether EB) 111-76-2	102-106	dermal	ND	ND	150 mg/kg/day - N	2160 mg/kg/day - N	ND
		inhalation	sys: decreased growth and hematological effects, dev: decreased maternal body, uterine, and liver weight; embryotoxicity; increased non-viable implantations; cardiac defects; skeletal malformations	ND	25 ppm (approximately 121 mg/m <sup>3</sup> ) - N	50 ppm (approximately 242 mg/m <sup>3</sup> ) - N (decreased body and uterine weight, embryotoxicity, hematological effects, skeletal malformations)	ND
		oral	sys: testicular atrophy, decreased body weight gain, increased kidney and liver weights; dev: maternal mortality, increased number of resorbed litters	ND	30 mg/kg/day - N (testicular atrophy)	1180 mg/kg/day - L (maternal mortality, increased number of resorbed litters)	ND
Butyl acetate 123-86-4	5, 6	dermal	ND	ND	60 mg/kg/day (W), 40 mg/kg/day (G) - L (serum chemistry) <sup>c</sup>	2031 mg/kg/day (W), 1341 mg/kg/day (G) - L (fetotoxicity and musculoskeletal abnormalities) <sup>c</sup>	ND
		inhalation	sys: changes in serum chemistry, fluctuations in blood pressure; dev: fetotoxicity, musculoskeletal abnormalities	ND	210 mg/m <sup>3</sup> - L (serum chemistry) <sup>d</sup>	7110 mg/m <sup>3</sup> - L (fetotoxicity and musculoskeletal abnormalities) <sup>d</sup>	ND
		oral	ND	ND	60 mg/kg/day (W), 40 mg/kg/day (G) - L (serum chemistry) <sup>c</sup>	2031 mg/kg/day (W), 1341 mg/kg/day (G) - L (fetotoxicity and musculoskeletal abnormalities) <sup>c</sup>	ND
Butyl carbitol 112-34-5	7-11	dermal	sys: blood and skin effects	ND	30 mg/kg/day - L (blood effects) <sup>d</sup>	2000 mg/kg/day - N <sup>d</sup>	ND
		inhalation	sys: liver effects	ND	2 ppm (approximately 13.3 mg/m <sup>3</sup> ) - N (liver effects) <sup>e</sup>	500 mg/kg/day (1750 mg/m <sup>3</sup> (W), 2652 mg/m <sup>3</sup> (G)) - N (decreased pup body weight) <sup>b</sup>	ND
		oral	sys: blood, kidney, liver, and reproductive effects, increased liver weight, changes in	ND	57 mg/kg/day - L (blood and clinical chemistry effects)	500 mg/kg/day - N (decreased pup body weight)	ND

Table 3-B.1 Health Hazard Results for Flexographic Ink Chemicals (continued)

Chemical name/ CAS number	Reference*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
C.I. Pigment Blue 15 147-14-8	12	dermal	ND	ND	6000 mg/kg/day - N <sup>b</sup>	ND	ND
		inhalation	ND	ND	6000 mg/kg/day (21,000 mg/m <sup>3</sup> (W), 31,818 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	ND	ND
		oral	ND	ND	6000 mg/kg/day - N <sup>f</sup>	ND	No effects were seen at the highest dose tested.
C.I. Pigment Green 7 1328-53-6	13	dermal	ND	ND	2750 mg/kg/day - L (decreased body weight) <sup>b</sup>	ND	Not reported to be a dermal sensitizer in guinea pigs.
		inhalation	ND	ND	2750 mg/kg/day (9625 mg/m <sup>3</sup> (W), 14,583 (G)) - L (decreased body weight) <sup>b</sup>	ND	ND
		oral	sys: decreased body weight	ND	2750 mg/kg/day - L (decreased body weight)	ND	ND
C.I. Pigment Red 23 6471-49-4	14	dermal	ND	ND	425 mg/kg/day - L (nephropathy, renal tubule hyperplasia) <sup>b</sup>	ND	ND
		inhalation	ND	ND	425 mg/kg/day (1488 mg/m <sup>3</sup> (W), 2254 mg/m <sup>3</sup> (G)) - L (nephropathy, renal tubule hyperplasia) <sup>b</sup>	ND	ND
		oral	sys: blood effects, nephropathy, renal tubule hyperplasia, forestomach epithelial hyperplasia	ND	425 mg/kg/day - L (nephropathy, renal tubule hyperplasia)	ND	ND
C.I. Pigment White 6 13463-67-7	2, 16	dermal	ND	6 mg/kg/day (premature aging) <sup>b</sup>	ND	ND	Not reported to be a dermal sensitizer in humans.
		inhalation	sys: respiratory effects, lung carcinogenicity (rat)	0.04 mg/m <sup>3</sup> (respiratory effects)	ND	ND	ND
		oral	sys: bile duct, lymphatic, and respiratory effects	6 mg/kg/day (bile duct, lymphatic, respiratory effects)	ND	ND	ND

Chemical name/ CAS number	Refer- ence*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
Citric acid 77-92-9	18	dermal	ND	ND	645 mg/kg/day - N <sup>b</sup>	6000 mg/kg/day - N <sup>b</sup>	ND
		inhalation	ND	ND	645 mg/kg/day (2258 mg/m <sup>3</sup> (W), 3420 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	6000 mg/kg/day (21,000 mg/m <sup>3</sup> (W), 31,818 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	ND
		oral	sys: decreased body weight gain, decreased survival	ND	645 mg/kg/day - N <sup>d</sup>	6000 mg/kg/day - N <sup>d</sup>	No effects were seen at the only doses tested in the systemic and developmental studies.
D&C Red No. 7 5281-04-9	19	dermal	ND	ND	100 mg/kg/day - L (decreased thymus weight, kidney lesions) <sup>b</sup>	1000 mg/kg/day - N <sup>b</sup>	ND
		inhalation	ND	ND	100 mg/kg/day (350 mg/m <sup>3</sup> (W), 530 mg/m <sup>3</sup> (G)) - L (decreased thymus weight, kidney lesions) <sup>b</sup>	1000 mg/kg/day (3500 mg/m <sup>3</sup> (W), 5303 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	ND
		oral	sys: thymus and reproductive effects, changes in clinical chemistry, kidney effects, decreased thymus weight	ND	100 mg/kg/day - L (decreased thymus weight, kidney lesions)	1000 mg/kg/day - N <sup>f</sup>	No effects were seen at the highest dose tested in the developmental study.
Dicyclohexyl phthalate 84-61-7	20	dermal	ND	ND	240 mg/kg/day - N <sup>b</sup>	290 mg/kg/day - N <sup>b</sup>	ND
		inhalation	ND	ND	240 mg/kg/day (840 mg/m <sup>3</sup> (W), 1273 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	290 mg/kg/day (1015 mg/m <sup>3</sup> (W), 1538 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	ND
		oral	sys: increased liver weight, increased liver enzyme activity, liver effects, testicular atrophy	ND	240 mg/kg/day - N <sup>f</sup>	290 mg/kg/day - N <sup>f</sup>	No effects were seen at the highest doses tested in the systemic and developmental studies.
Dioctyl sulfosuccinate, sodium salt 577-11-7	21, 22	dermal	ND	ND	ND	60 mg/kg/day - N (decreased pup body weight) <sup>b</sup>	Reported to be a dermal sensitizer to humans. SAT: Low to Moderate
		inhalation	ND	ND	ND	60 mg/kg/day (210 mg/m <sup>3</sup> (W), 318 mg/m <sup>3</sup> (G)) - N (decreased pup body weight) <sup>b</sup>	ND
		oral	sys: death, gastrointestinal and neurotoxic effects (dose unclear); dev: decreased pup body weight and weight gain	ND	ND	60 mg/kg/day - N (decreased pup body weight)	ND

Table 3-B.1 Health Hazard Results for Flexographic Ink Chemicals (continued)

Chemical name/ CAS number	Reference*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide 75980-60-8	23, 24	dermal	ND	ND	100 mg/kg/day - N (decreased body weight and testes size, blood effects) <sup>b</sup>	ND	ND
		inhalation	ND	ND	100 mg/kg/day (350 mg/m <sup>3</sup> (W), 530 mg/m <sup>3</sup> (G)) - N (decreased body weight and testes size, blood effects) <sup>b</sup>	ND	ND
		oral	sys: decreased body weight, increased food consumption, blood and reproductive effects, reduced testes size, scale formation	ND	100 mg/kg/day - N (decreased body weight and testes size, blood effects)	ND	ND
Dipropylene glycol methyl ether 34590-94-8	25-27	dermal	sys: neurotoxic effects	ND	5 ml/kg/day (approximately 4750 mg/kg/day) - N (neurotoxic effects) <sup>g</sup>	ND	Not reported to be a dermal sensitizer in humans.
		inhalation	sys: decreased growth, liver, and neurotoxic effects, increased kidney weight	ND	200 ppm (approximately 1213 mg/m <sup>3</sup> ) - L (increased kidney weight) <sup>e</sup>	ND	ND
		oral	ND	ND	1000 mg/kg/day - N <sup>d</sup>	ND	No effects were seen at the only dose tested.
Distillates (petroleum), hydrotreated light 64742-47-8	15	dermal	sys: skin carcinogenicity (mice)	ND	ND	ND	Oral LD <sub>50</sub> in rats = 8532 mg/kg <sup>h</sup> ; dermal LD <sub>50</sub> in rabbits > 5000 mg/kg. SAT report indicates Low to Moderate concern for skin, eye, and mucous membrane irritation, inhalation.
		oral	ND	ND	ND	ND	
Distillates (petroleum), solvent-refined light paraffinic 64741-89-5	28, 29	dermal	sys: skin effects, benign skin tumors (mice)	ND	0.05 ml 2x/week (approximately 400 mg/kg/day) - L (skin irritation) <sup>i</sup>	ND	Reported to be a dermal sensitizer in guinea pigs.
		inhalation	ND	ND	400 mg/kg/day (1400 mg/m <sup>3</sup> (W), 2121 mg/m <sup>3</sup> (G)) - L (skin irritation) <sup>j</sup>	ND	ND
		oral	ND	ND	400 mg/kg/day - L (skin irritation) <sup>j</sup>	ND	ND

Chemical name/ CAS number	Refer- ence*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
Ethanol 64-17-5	30, 31	dermal	ND	ND	8000 mg/kg/day - L (liver effects) <sup>b</sup>	171 mg/kg/day - N (increased spontaneous abortions) <sup>b</sup>	ND
		inhalation	sys: blood, liver, neurotoxic, and reproductive effects, decreased cellularity of the spleen, thymus, and bone marrow; dev: fetal malformations	ND	5653 mg/m <sup>3</sup> - N	30,148 mg/m <sup>3</sup> - N (increased incidence of malformations)	ND
		oral	sys: endocrine, gastro-intestinal, liver, reproductive, CNS, pancreatic, and rectal effects, disrupted hormone metabolism and immune response, altered left ventricular function; stomach, lymph, lung, pituitary, adrenal, pancreatic, mammary and testes carcinogenicity (mice), oral, pharyngeal, laryngeal, esophageal, rectal, and breast carcinogenicity (humans), liver carcinogenicity (mice and humans); dev: spontaneous abortions, decreased pre- and post-natal survival, increased fetal malformations, inhibited fetal growth and development, altered brain weight, retarded skeletal and muscle development and muscle growth, CNS structural defects, altered gonad growth and development, disturbances in sexual behavior and performance, hormone disruptions, decreased ovarian function, behavioral and neuromotor alterations, Fetal Alcohol Syndrome (FAS)	ND	8000 mg/kg/day - L (liver effects)	1200 mg/kg once/week (171 mg/kg/day) - N (increased spontaneous abortions) <sup>k</sup>	IARC (1988) has concluded that there is inadequate evidence for carcinogenicity of ethanol and of alcoholic beverages in experimental animals, but there is sufficient evidence for carcinogenicity of alcoholic beverages in humans. Ethanol is classified by IARC as a Group 1 carcinogen based on the occurrence of malignant tumors of the oral cavity, pharynx, larynx, esophagus, and liver that have been causally related to the consumption of alcoholic beverages.
Ethanolamine 141-43-5	32-35	dermal	ND	ND	500 mg/kg/day - N <sup>b</sup>	50 mg/kg/day - L (growth retardation, malformations) <sup>b</sup>	Reported to be a moderate skin sensitizer in guinea pigs.
		inhalation	sys: respiratory irritation, kidney, liver, neurotoxic, and respiratory effects	ND	5 ppm (approximately 12.5 mg/m <sup>3</sup> ) - L (skin irritation, decreased body weight, neurotoxic effects) <sup>e</sup>	50 mg/kg/day (175 mg/m <sup>3</sup> (W), 265 mg/m <sup>3</sup> (G)) - L (growth retardations, malformations) <sup>b</sup>	ND
		oral	sys: neurotoxic and reproductive effects, altered liver and kidney weights; dev: intrauterine deaths, malformations, decreased fetal weight, growth retardation	ND	500 mg/kg/day - N <sup>d</sup>	50 mg/kg/day - L (growth retardation, malformations)	No effects were seen at the only dose tested in the systemic study.

Table 3-B.1 Health Hazard Results for Flexographic Ink Chemicals (continued)

Chemical name/ CAS number	Reference*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
Ethyl acetate 141-78-6	2, 36	dermal	ND	0.9 mg/kg/day (mortality and body weight loss) <sup>b</sup>	ND	ND	ND
		inhalation	sys: blood, cardiovascular, gastrointestinal, kidney, liver, neurotoxic, and respiratory effects, decreased spleen and liver weight, increased adrenal, lung, and kidney weight	ND	1261 mg/m <sup>3</sup> - L (degeneration of nasal mucosa)	ND	ND
		oral	sys: excess salivation, decreased food consumption, neurotoxic and respiratory effects, mortality, decreased body and organ weights	0.9 mg/kg/day (mortality and body weight loss)	ND	ND	ND
Ethyl carbitol 111-90-0	37-40	dermal	ND	ND	5 mg/kg/day - L (blood effects, increased kidney weight) <sup>b</sup>	6000 mg/kg/day - N	Not reported to be a dermal sensitizer in humans.
		inhalation	ND	ND	5 mg/kg/day (17.5 mg/m <sup>3</sup> (W), 26.5 mg/m <sup>3</sup> (G) - L (blood effects, increased kidney weight) <sup>b</sup>	1500 mg/kg/day (5250 mg/m <sup>3</sup> (W), 7955 mg/m <sup>3</sup> (G) - N (decreased motile sperm, increased liver weight, decreased brain weight in offspring) <sup>b</sup>	ND
		oral	sys: decreased food consumption, bladder, blood, kidney, liver, neurotoxic, reproductive and spleen effects, altered blood chemistry, increased kidney weight; dev: decreased motile sperm, increased liver weight, decreased brain weight and birth weight in offspring	ND	5 mg/kg/day - L (blood effects, increased kidney weight)	1.25% in diet (approximately 1500 mg/kg/day) - N (decreased motile sperm, increased liver weight, decreased brain weight in offspring) <sup>l</sup>	Length of dosing period for systemic study was not specified.



Chemical name/ CAS number	Reference*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
2-Ethylhexyl diphenyl phosphate 1241-94-7	41, 42	dermal	ND	ND	136 mg/kg/day - L (increased liver weight, increased serum triglycerides) <sup>b</sup>	144 mg/kg/day - L (increased liver weight in pups) <sup>b</sup>	ND
		inhalation	ND	ND	136 mg/kg/day (476 mg/m <sup>3</sup> (W), 721 mg/m <sup>3</sup> (G)) - L (increased liver weight, increased serum triglycerides) <sup>b</sup>	144 mg/kg/day (504 mg/m <sup>3</sup> (W), 764 mg/m <sup>3</sup> (G)) - L (increased liver weight in pups) <sup>b</sup>	ND
		oral	sys: decreased body weight gain, liver, reproductive, and spleen effects, increased adrenal weight, altered liver weight, changes in serum chemistry; dev: decreased pup survival, malformations, unossified sternalae, extra ribs, increased adrenal and liver weight, decreased spleen weight	ND	136 mg/kg/day - L (increased liver weight, increased serum triglycerides)	144 mg/kg/day - L (increased liver weight in pups)	The systemic LOAEL is based upon a subacute study.
Glycerol propoxylate triacrylate 52408-84-1	43	dermal	sys: tissue necrosis at application site, decreased body weight, neurotoxic and respiratory effects	ND	0.1 ml/animal/day (426 mg/kg/day) - L (dermal irritation and necrosis, decreased body weight gain) <sup>m</sup>	ND	ND
		inhalation	ND	ND	426 mg/kg/day (1491 mg/m <sup>3</sup> (W), 2259 mg/m <sup>3</sup> (G)) - L (dermal irritation and necrosis, decreased body weight gain) <sup>j</sup>	ND	ND
		oral	ND	ND	426 mg/kg/day - L (dermal irritation and necrosis, decreased body weight gain) <sup>j</sup>	ND	ND
n-Heptane 142-82-5	44, 45	dermal	ND	ND	1000 mg/kg/day - N (enzyme and gastrointestinal effects) <sup>b</sup>	ND	ND
		inhalation	sys: auditory and neurotoxic effects, altered serum chemistry	ND	1635 mg/m <sup>3</sup> - L (neurotoxic effects)	ND	ND
		oral	sys: gastrointestinal effects, altered enzyme levels, increased liver weight	ND	1000 mg/kg/day - N (enzyme and gastrointestinal effects)	ND	ND

Table 3-B.1 Health Hazard Results for Flexographic Ink Chemicals (continued)

Chemical name/ CAS number	Reference*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
1,6-Hexanediol diacrylate 13048-33-4	46-48	dermal	ND	ND	ND	750 mg/kg/day - L (increased incidence of skeletal variations) <sup>b</sup>	Reported to be dermal sensitizer in animal studies. SAT: Moderate
		inhalation	ND	ND	ND	750 mg/kg/day (2625 mg/m <sup>3</sup> (W), 3977 mg/m <sup>3</sup> (G)) - L (increased incidence of skeletal variations) <sup>b</sup>	Rats exposed to 90 mg/m <sup>3</sup> for 6 hours exhibited no significant changes in clinical signs or gross necropsy.
		oral	dev: increase in skeletal variations	ND	ND	750 mg/kg/day - L (increased incidence of skeletal variations) <sup>d</sup>	ND
2-Hydroxy-2-methylpropiophenone 7473-98-5	49, 50	dermal	ND	ND	100 mg/kg/day - N (increased liver weight) <sup>b</sup>	ND	Reported to be a dermal sensitizer in guinea pigs.
		inhalation	ND	ND	100 mg/kg/day (350 mg/m <sup>3</sup> (W), 530 mg/m <sup>3</sup> (G)) - N (increased liver weight) <sup>b</sup>	ND	ND
		oral	sys: liver effects, increased liver and kidney weights	ND	100 mg/kg/day - N (increased liver weight)	ND	The systemic NOAEL is based upon a subacute study.
Hydroxypropyl acrylate 25584-83-2	51	dermal	ND	ND	7.7 mg/kg/day (W), 5.1 mg/kg/day (G) - L (respiratory lesions) <sup>c</sup>	ND	ND
		inhalation	sys: respiratory effects	ND	27 mg/m <sup>3</sup> - L (respiratory lesions)	ND	ND
		oral	ND	ND	7.7 mg/kg/day (W), 5.1 mg/kg/day (G) - L (respiratory lesions) <sup>c</sup>	ND	ND
Isobutanol 78-83-1	2, 52, 53	dermal	ND	0.3 mg/kg/day (neurotoxic effects) <sup>b</sup>	ND	ND	ND
		inhalation	sys: blood and neurotoxic effects, changes in enzyme levels; dev: cardiac septal defects	ND	0.1 mg/m <sup>3</sup> - N (blood effects, neurotoxic effects)	ND	ND

Chemical name/ CAS number	Reference*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
		oral	ND	0.3 mg/kg/day (neurotoxic effects)	ND	ND	ND
Isopropanol 67-63-0	54-59	dermal	sys: blood and skin effects, tissue necrosis at application site, increased kidney and liver weight	ND	157 mg/kg/day - L (blood and skin effects, increased kidney and liver weight)	0.015 mg/kg/day - N (decreased embryo survival, developmental anomalies of the CNS) <sup>b</sup>	Reported to be a dermal sensitizer to humans. IARC (1987) has classified isopropanol as a Group 3 compound, not classifiable as to its carcinogenicity to humans based on inadequate evidence in humans and experimental animals.
		inhalation	sys: liver, neurotoxic, reproductive, respiratory, and spleen effects, changes in enzyme levels and clinical and urine chemistry; dev: fetal death, musculoskeletal abnormalities, fetotoxicity	ND	0.66 mg/m <sup>3</sup> - N (neurotoxic effects, enzyme, urine, blood, respiratory, liver, and spleen effects)	3500 ppm (approximately 8601 mg/m <sup>3</sup> ) - L (fetotoxicity) <sup>e</sup>	
		oral	sys: decreased body weight gain, kidney, liver, and reproductive effects; dev: reduced pup growth	ND	0.015 mg/kg/day - N (liver and kidney effects)	0.015 mg/kg/day - N (decreased embryo survival, developmental anomalies of the CNS) <sup>b</sup>	
Kaolin 1332-58-7	60, 61	dermal	ND	ND	10,000 mg/kg/day - L (blood effects) <sup>b</sup>	10,000 mg/kg/day - L (decreased pup body weight) <sup>b</sup>	ND
		inhalation	sys: respiratory effects, increased lung weight, lung carcinogenicity (rat)	ND	3 mg/m <sup>3</sup> - L (lung lesions)	10,000 mg/kg/day (35,000 mg/m <sup>3</sup> (W), 53,030 mg/m <sup>3</sup> (G)) - L (decreased pup body weight) <sup>b</sup>	ND
		oral	sys: blood effects; dev: decreased pup body weight	ND	10,000 mg/kg/day - L (blood effects) <sup>d</sup>	10,000 mg/kg/day - L (decreased pup body weight) <sup>d</sup>	Hematology was the only non-reproductive parameter evaluated.
2-Methyl-4'-(methylthio)-2-morpholino-propiophenone 71868-10-5	62	dermal	ND	ND	75 mg/kg/day - N (neurotoxic effects, cataracts) <sup>b</sup>	ND	ND
		inhalation	ND	ND	75 mg/kg/day (263 mg/m <sup>3</sup> (W), 398 mg/m <sup>3</sup> (G)) - N (neurotoxic effects, cataracts) <sup>b</sup>	ND	ND
		oral	sys: decreased body weight and food consumption, blood, liver, and neurotoxic effects, nerve fiber degeneration, cataracts	ND	75 mg/kg/day - N (neurotoxic effects, cataracts) <sup>d</sup>	ND	ND

Table 3-B.1 Health Hazard Results for Flexographic Ink Chemicals (continued)

Chemical name/ CAS number	Reference*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
Mineral oil 8012-95-1	63	dermal	ND	ND	1676 mg/kg/day - N <sup>b</sup>	ND	ND
		inhalation	ND	ND	1676 mg/kg/day (5866 mg/m <sup>3</sup> (W), 8888 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	ND	ND
		oral	sys: respiratory effects	ND	1676 mg/kg/day - N <sup>d</sup>	ND	No effects were seen at the only dose tested.
Phosphine oxide, bis(2,6-dimethoxy benzoyl)(2,4,4-trimethylpentyl)- 145052-34-2	64, 65	dermal	ND	ND	10 mg/kg/day - N (neurotoxic effects, increased liver weight, decreased thymus weight, squamous skin on feet) <sup>b</sup>	ND	Reported to be an extreme skin sensitizer in guinea pigs.
		inhalation	ND	ND	10 mg/kg/day (35 mg/m <sup>3</sup> (W), 53 mg/m <sup>3</sup> (G)) - N (neurotoxic effects, increased liver weight, decreased thymus weight, squamous skin on feet) <sup>b</sup>	ND	ND
		oral	sys: neurotoxic, decreased food consumption and body weight, adrenal, blood, and liver effects, changes in enzyme levels and serum chemistry, increased liver and adrenal weight, decreased thymus weight, squamous skin on feet, tail, and scrotum	ND	10 mg/kg/day - N (neurotoxic effects, increased liver weight, decreased thymus weight, squamous skin on feet)	ND	The systemic NOAEL is based upon a subacute study.
Polyethylene glycol 25322-68-3	66, 67	dermal	ND	ND	1580 mg/kg/day - N (decreased body weight, liver and kidney lesions) <sup>b</sup>	ND	Not reported to be a dermal sensitizer based on studies with several materials.
		inhalation	ND	ND	1580 mg/kg/day (5530 mg/m <sup>3</sup> (W), 8379 mg/m <sup>3</sup> (G)) - N (decreased body weight, liver and kidney lesions) <sup>b</sup>	ND	ND
		oral	sys: decreased body weight, kidney and liver effects	ND	1580 mg/kg/day - N (decreased body weight, liver and kidney lesions)	ND	NOAEL is based upon a study with polyethylene glycol with a MW of 400.

Chemical name/ CAS number	Reference*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
Polytetrafluoro-ethylene 9002-84-0	54, 74, 75	dermal	ND	ND	6000 mg/kg/day - N <sup>b</sup>	ND	Not reported to be a skin sensitizer (species not indicated).
		inhalation	sys: blood, neurotoxic, and respiratory effects, changes in urine chemistry	ND	6000 mg/kg/day (21,000 mg/m <sup>3</sup> (W), 31,818 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	ND	IARC (1987) has classified polytetrafluoroethylene as a Group 3 compound, not classifiable as to its carcinogenicity, based on no adequate evidence in humans and inadequate evidence in experimental animals.
		oral	ND	ND	6000 mg/kg/day - N <sup>d</sup>	ND	The systemic NOAEL is based upon a subacute study. No effects were seen at the only dose tested.
Propanol 71-23-8	76-79	dermal	ND	ND	57.1 mg/kg/day) - L (reduced survival, liver and bone marrow effects) <sup>b</sup>	2458 mg/kg/day (W), 1622 mg/kg/day (G) - N (decreased fetal body weight, increased litters with malformations) <sup>c</sup>	ND
		inhalation	sys: liver and reproductive effects; dev: decreased fetal body weight, malformations	ND	165 mg/m <sup>3</sup> - L (liver lesions)	3500 ppm (approximately 8603 mg/m <sup>3</sup> ) - N (decreased fetal body weight, increased litters with malformations) <sup>e</sup>	The systemic LOAEL is based upon a subacute study.
		oral	sys: liver, bone marrow, and neurotoxic effects, increased liver weight, decreased survival	ND	200 mg/kg twice/week (approximately 57.1 mg/kg/day) - L (reduced survival, liver and bone marrow effects) <sup>k</sup>	2458 mg/kg/day (W), 1622 mg/kg/day (G) - N (decreased fetal body weight, increased litters with malformations) <sup>c</sup>	The U.S. EPA (1987) has proposed that propanol be given a Group C classification, possible human carcinogen, based on no evidence of carcinogenicity in humans and limited evidence of carcinogenicity in experimental animals.

Table 3-B.1 Health Hazard Results for Flexographic Ink Chemicals (continued)

Chemical name/ CAS number	Reference*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
Propyl acetate 109-60-4	80, 81	dermal	ND	ND	ND	ND	Derma! LD <sub>50</sub> > 20 mL/kg (species not indicated). SAT: Low to Moderate
		inhalation	ND	ND	ND	ND	ND
		oral	ND	ND	ND	ND	Oral LD <sub>50</sub> 's range from 6.64 to 9.37 g/kg for rats, mice, and rabbits.
Propylene glycol methyl ether 107-98-2	68-70	dermal	sys: increased mortality, blood, neurotoxic, and skin effects, altered kidney weight	0.7 mg/kg/day (liver and kidney effects, increased liver and kidney weights) <sup>b</sup>	ND	1580 mg/kg/day (W), 1043 mg/kg/day (G) - N (delayed ossification) <sup>c</sup>	Not reported to be a dermal sensitizer in guinea pigs.
		inhalation	sys: decreased growth, liver, neurotoxic, reproductive, and respiratory effects, increased liver and kidney weights; dev: delayed ossification of vertebrae, musculoskeletal abnormalities	2 mg/m <sup>3</sup> (neurotoxic effects)	ND	1500 ppm (approximately 5530 mg/m <sup>3</sup> ) - N (delayed ossification) <sup>e</sup>	ND
		oral	sys: decreased body weight and body weight gain, decreased food consumption, blood, neurotoxic, kidney, liver, and reproductive effects, and increased liver and kidney weight, spermiophages in the epididymus	0.7 mg/kg/day (liver and kidney effects, increased liver and kidney weights)	ND	1580 mg/kg/day (W), 1043 mg/kg/day (G) - N (delayed ossification) <sup>c</sup>	ND
Propylene glycol propyl ether 1569-01-3	71-73	dermal	ND	ND	41 mg/kg/day (W), 27 mg/kg/day (G) - N <sup>c</sup>	1034 mg/kg/day (W), 683 mg/kg/day (G) - N (poorly ossified hind-limb phalanges) <sup>c</sup>	ND
		inhalation	sys: decreased body weight and body weight gain, corneal opacity and injury, neurotoxic effects, increased kidney and liver weight; dev: poorly ossified hind-limb phalanges	ND	145 mg/m <sup>3</sup> - N	3620 mg/m <sup>3</sup> - N (poorly ossified hind-limb phalanges)	483 mg/m <sup>3</sup> caused irreversible eye lesions in F344 rats, and potentially reversible eye lesions in SD rats and rabbits.
		oral	ND	ND	41 mg/kg/day (W), 27 mg/kg/day (G) - N <sup>c</sup>	1034 mg/kg/day (W), 683 mg/kg/day (G) - N (poorly ossified hind-limb phalanges) <sup>c</sup>	ND

Chemical name/ CAS number	Refer- ence*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
Resin, acrylic NK	82-85	dermal	ND	ND	1500 mg/kg/day - N <sup>f</sup>	4000 mg/kg/day - N <sup>b</sup>	NOAELs and toxicity endpoints are based on studies conducted on acrylic acid homopolymer, CAS# 9003-01-4.
		inhalation	sys: respiratory effects, lung carcinogenicity (rats)	ND	0.05 mg/m <sup>3</sup> - N (respiratory effects)	10 mg/m <sup>3</sup> - N <sup>f</sup>	
		oral	sys: decreased body weight gain, kidney effects, changes in urine chemistry	ND	3000 mg/kg/day - N <sup>f</sup>	4000 mg/kg/day - N <sup>f</sup>	
Silica 7631-86-9	86, 101	dermal	ND	ND	ND	ND	Dose was not extrapolated from inhalation to oral or dermal because treatment-related effects were confined to the lungs. IARC (1997) has classified amorphous silica as a Group 3 compound, not classifiable as to its carcinogenicity to humans, based on inadequate evidence in humans and experimental animals.
		inhalation	sys: death, lymphatic and respiratory effects, lung carcinogenicity (rats and humans)	ND	0.1 mg/m <sup>3</sup> crystalline silica - N (silicosis)	ND	
		oral	ND	ND	ND	ND	
Silicone oil 63148-62-9	87-90	dermal	sys: decreased testes weight and size, spermatogenic depression, tubular atrophy; dev: increased resorptions, malformations	ND	200 mg/kg/day - L (death, decreased testes weight, spermatogenic depression)	200 mg/kg/day - L (increased incidence of resorptions)	ND
		inhalation	ND	ND	200 mg/kg/day (700 mg/m <sup>3</sup> (W), 1061 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	200 mg/kg/day (700 mg/m <sup>3</sup> (W), 1061 mg/m <sup>3</sup> (G)) - L (increased incidence of resorptions) <sup>j</sup>	Exposure of rats, dogs, and guinea pigs to 2,120 mg/m <sup>3</sup> for 6 hours resulted in neurotoxic and respiratory effects.
		oral	sys: increased food consumption, gastrointestinal effects, increased spleen weight, decreased seminal vesicle weight	ND	1% in the diet (approximately 200 mg/kg/day) - N <sup>i</sup>	200 mg/kg/day - L (increased incidence of resorptions) <sup>j</sup>	ND

Table 3-B.1 Health Hazard Results for Flexographic Ink Chemicals (continued)

Chemical name/ CAS number	Refer- ence*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
Styrene 100-42-5	2, 91, 92	dermal	ND	0.2 mg/kg/day (blood effects) <sup>b</sup>	ND	300 mg/kg/day - N <sup>b</sup>	ND
		inhalation	sys: nasal and lung irritation, blood, liver, neurotoxic, and respiratory effects, increased liver weight, mammary carcinogenicity (rats); dev: increased resorptions, fetal deaths, decreased pup body weight, decreased levels of fetal cerebral serotonin and 5-hydroxyindoleacetic acid	1.0 mg/m <sup>3</sup> (neurotoxic effects in humans)	ND	50 ppm (approximately 213 mg/m <sup>3</sup> ) - L (decreased pup body weight) <sup>e</sup>	ND
		oral	sys: blood, liver, neurotoxic, and respiratory effects, lung and liver carcinogenicity (mice)	0.2 mg/kg/day (blood effects)	ND	300 mg/kg/day - N	ND
Trimethylol- propane ethoxylate triacylate 28961-43-5	93	dermal	ND	ND	ND	1000 mg/kg/day - N <sup>b</sup>	SAT: Low to Moderate
		inhalation	sys: liver and spleen effects; dose unclear	ND	ND	1000 mg/kg/day (3500 mg/m <sup>3</sup> (W), 5303 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	ND
		oral	ND	ND	ND	1000 mg/kg/day - N <sup>d</sup>	No effects were seen at the only dose tested.
Trimethylol- propane triacylate 15625-89-5	94-97	dermal	sys: decreased body weight, skin and neurotoxic effects, changes in clinical chemistry, altered organ weights	ND	0.75 mg/kg/day - N (dermal lesions)	500 mg/kg/day - N <sup>b</sup>	Reported to be a mild dermal sensitizer in guinea pigs.
		inhalation	sys: decreased body weight, respiratory effects	ND	5.7 mg/m <sup>3</sup> - L (respiratory effects, body weight loss)	500 mg/kg/day (1750 mg/m <sup>3</sup> (W), 2652 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	ND
		oral	ND	ND	1.6 mg/kg/day (W), 1.1 mg/kg/day (G) - L (respiratory effects, body weight loss) <sup>c</sup>	500 mg/kg/day - N	ND



Chemical name/ CAS number	Refer- ence*	Exposure route	Toxicity endpoints <sup>a</sup>	RfD/RfC	Critical toxicity value**		Comment
					Systemic	Developmental	
Urea 57-13-6	98-100	dermal	ND	ND	6750 mg/kg/day - N <sup>b</sup>	50,000 mg/kg/day - N <sup>b</sup>	Not reported to be a dermal sensitizer (species not indicated).
		inhalation	ND	ND	6750 mg/kg/day (23,625 mg/m <sup>3</sup> (W), 35,795 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	50,000 mg/kg/day (175,000 mg/m <sup>3</sup> (W), 265,152 mg/m <sup>3</sup> (G)) - N <sup>b</sup>	ND
		oral	ND	ND	6750 mg/kg/day - N	50,000 mg/kg/day - N	No effects were seen at any doses tested in the systemic and developmental studies

Table 3-B.1 Health Hazard Results for Flexographic Ink Chemicals (continued)

## TABLE 3-B.1 FOOTNOTES

ABBREVIATIONS: NK, not known; CTV, critical toxicity value; N, NOAEL or NOAEC; L, LOAEL or LOAEC; sys, systemic effects; dev, developmental effects; W, worker; G, general population

\*Most of the references were developed from online database searches conducted during July and August 1997. In most cases, the primary references were not reviewed.

\*\*The critical toxicity value (CTV) is the NOAEL, NOAEC, LOAEL, or LOAEC. The CTV is used with exposure data for quantitative evaluation of risk.

<sup>a</sup> Provides a complete listing for all endpoints/toxic effects found within the hazard profiles. Does not indicate severity of effects.

<sup>b</sup> Inhalation or dermal CTV or RfD is based on oral data. Worker inhalation values (W) have been converted from mg/kg/day to mg/m<sup>3</sup> using the following conversion, based upon default human body weight (70 kg) and respiratory rate (20 m<sup>3</sup>/day):

$$\text{mg/m}^3 = \text{mg/kg/day} \times 1 \text{ day}/20 \text{ m}^3 \times 70 \text{ kg}$$

General population inhalation values (G) have been converted from mg/kg/day using the following conversions, based upon default human body weight (70 kg) and respiratory rate (13.2 m<sup>3</sup>/day):

$$\text{mg/m}^3 = \text{mg/kg/day} \times 1 \text{ day}/13.2 \text{ m}^3 \times 70 \text{ kg}$$

<sup>c</sup> Oral or dermal CTV is based upon inhalation data. Worker oral or dermal values (W) have been converted from mg/m<sup>3</sup> to mg/kg/day using the following conversion, based upon default human body weight (70 kg) and respiratory rate (20 m<sup>3</sup>/day):

$$\text{mg/kg/day} = \text{mg/m}^3 \times 20 \text{ m}^3/1 \text{ day} \times 1/70 \text{ kg}$$

General population oral or dermal values (G) have been converted from mg/m<sup>3</sup> to mg/kg/day using the following conversion, based upon default human body weight (70 kg) and respiratory rate (13.2 m<sup>3</sup>/day):

$$\text{mg/kg/day} = \text{mg/m}^3 \times 13.2 \text{ m}^3/1 \text{ day} \times 1/70 \text{ kg}$$

<sup>d</sup> Only dose tested.

<sup>e</sup> Original data given in ppm, converted to mg/m<sup>3</sup> using the following conversion:

$$\text{mg/m}^3 = [\text{ppm} \times \text{molecular weight (grams)}] \div 24.45$$

<sup>f</sup> Highest dose tested

<sup>g</sup> Original dose was given in ml/kg/day and was converted to mg/kg/day using the following conversion:

$$\text{mg/kg/day} = \text{ml/kg/day} \times \text{density (grams/ml)} \times 1000 \text{ mg/gram}$$

<sup>h</sup> Available LD<sub>50</sub>s given only for those chemicals for which no other toxicity information was found.

<sup>i</sup> Original value for petroleum distillates was given as 0.05 ml 2x/week and has been converted to mg/kg/day using the following conversion, using a default mouse body weight of 25 grams, a dose of 0.01 ml/day, and assuming a density of 1 gram/ml:

$$\text{mg/kg/day} = 0.01 \text{ ml}/.025 \text{ kg} \times 1/\text{day} \times 1 \text{ gram/ml} \times 1000 \text{ mg/gram} = 400 \text{ mg/kg/day}$$

<sup>j</sup> Oral or inhalation CTV or RfD is based upon dermal data. Worker inhalation values (W) have been converted from mg/kg/day to mg/m<sup>3</sup> using the following conversion, based upon default human body weight (70 kg) and respiratory rate (20 m<sup>3</sup>/day):

$$\text{mg/m}^3 = \text{mg/kg/day} \times 1 \text{ day}/20 \text{ m}^3 \times 70 \text{ kg}$$

General population inhalation values (G) have been converted from mg/kg/day to mg/m<sup>3</sup> using the following conversion, based upon default human body weight (70 kg) and respiratory rate (13.2 m<sup>3</sup>/day):

$$\text{mg/m}^3 = \text{mg/kg/day} \times 1 \text{ day}/13.2 \text{ m}^3 \times 70 \text{ kg}$$

<sup>k</sup> Original dose was given as 1x or 2x/week and has been converted to mg/kg/day by dividing the total weekly dose by 7 days/week.

<sup>l</sup> Original exposure was given as % in diet. For studies with humans, conversions were done by the performing laboratory. For mice, values were converted using a default body weight of 25 grams and average food intake of 3 grams/day:

$$\text{mg/kg/day} = \% \text{ in diet}/100 \times 3 \text{ grams/day} \div 0.025 \text{ kg} \times 1000 \text{ mg/gram}$$

<sup>m</sup> Original value was given as ml/animal/day and has been converted to mg/kg/day using the following conversion, based upon default rat body weight (250 g) and density of 1.064 grams/ml:

$$\text{mg/kg/day} = 0.1 \text{ ml}/.25 \text{ kg} \times 1/\text{day} \times 1.064 \text{ grams/ml} \times 1000 \text{ mg/gram}$$

**Table 3-B.2 SAT Reports and Available Acute Data for Chemicals with No or Inadequate Hazard Data**

Chemical name and CAS number	Summary of SAT report and available acute data	Reference
<b>SAT reports <sup>a</sup> for chemicals with no or inadequate toxicity data.</b>		
Acrylated epoxy polymer NK	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. If the polymer is terminated with acrylates, there is concern for mutagenicity, oncogenicity, developmental toxicity, and dermal and respiratory sensitization. Low concern for other effects.	
Acrylated oligoamine polymer NK	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. If the polymer is terminated with acrylates, there is concern for mutagenicity, oncogenicity, developmental toxicity, and dermal and respiratory sensitization. Low concern for other effects.	
Acrylated polyester polymer #1 NK	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. If the polymer is terminated with acrylates, there is concern for mutagenicity, oncogenicity, developmental toxicity, and dermal and respiratory sensitization. Low concern for other effects.	
Acrylated polyester polymer #2 NK	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. If the polymer is terminated with acrylates, there is concern for mutagenicity, oncogenicity, developmental toxicity, and dermal and respiratory sensitization. Low concern for other effects.	
Acrylic acid-butyl acrylate-methyl methacrylate-styrene polymer 27306-39-4	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. Low concern for other effects.	
Acrylic acid polymer, acidic #1 NK	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. Low concern for other effects.	
Acrylic acid polymer, acidic #2 NK	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. Low concern for other effects.	
Acrylic acid polymer, insoluble NK	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. Low concern for other effects.	
Alcohols, C11-C15-secondary, ethoxylated 68131-40-8	Moderate concern overall. This material is reported to be a severe skin irritant. The surfactant activity of this chemical may result in eye irritation and lung effects.	
Amides, tallow, hydrogenated 61790-31-6	Low concern overall.	
Butyl acrylate-methacrylic acid-methyl methacrylate polymer 25035-69-2	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. Low concern for other effects.	
C.I. Basic Violet 1, molybdatephosphate 67989-22-4	Low to Moderate concern for oncogenicity, mutagenicity, and developmental toxicity.	
C.I. Basic Violet 1, molybdatetungstate-phosphate 1325-82-2	Low to Moderate concern for oncogenicity, genotoxicity, developmental toxicity, immunosuppression, methemoglobinemia, and liver effects.	

## APPENDIX 3-B

## HUMAN HEALTH AND ECOLOGICAL HAZARD RESULTS

Chemical name and CAS number	Summary of SAT report and available acute data	Refer- ence
C.I. Pigment Blue 61 1324-76-1	Low concern overall.	
C.I. Pigment Red 48, barium salt (1:1) 7585-41-3	4 hour LC <sub>50</sub> in rats = 5420 mg/m <sup>3h</sup> . Low to Moderate concern for oncogenicity, neurotoxicity and developmental toxicity.	15
C.I. Pigment Red 48, calcium salt (1:1) 7023-61-2	Low to Moderate concern for oncogenicity.	
C.I. Pigment Red 52, calcium salt (1:1) 17852-99-2	Low to Moderate concern for mutagenicity, developmental toxicity, and oncogenicity.	
C.I. Pigment Red 269 67990-05-0	Low concern overall.	
C.I. Pigment Violet 23 6358-30-1	Low concern overall.	
C.I. Pigment Violet 27 12237-62-6	Low to Moderate concern for oncogenicity, mutagenicity, developmental toxicity, and neurotoxicity.	
C.I. Pigment White 7 1314-98-3	Low to Moderate concern for mutagenicity, developmental toxicity, and immunotoxicity.	
C.I. Pigment Yellow 14 5468-75-7	No clinical signs of toxicity were seen in rats exposed orally to 11,000 mg/kg. Low concern overall unless exposed to temperatures greater than 200C. There is Low to Moderate concern for oncogenicity, mutagenicity, neurotoxicity, and liver effects.	17
C.I. Pigment Yellow 74 6358-31-2	Low concern overall.	
Dipropylene glycol diacrylate 57472-68-1	Oral LD <sub>50</sub> in rats = 4.6 g/kg. Moderate concern for genotoxicity, neurotoxicity, oncogenicity, developmental and reproductive effects, dermal and respiratory sensitization, and skin and eye irritation.	
Erucamide 112-84-5	Low concern overall.	
Ethoxylated tetramethyldecyldiol 9014-85-1	Low to Moderate concern for eye, skin, lung and mucous membrane irritation, and neurotoxic, liver, and kidney effects. The surfactant nature of this material may cause lung effects if inhaled.	
Ethyl 4-dimethyl-aminobenzoate 10287-53-3	Low to Moderate concern for genotoxicity, oncogenicity, neurotoxicity, cardiac sensitization, and developmental toxicity.	
Fatty acid, dimer-based polyamide NK	Low concern overall.	
Fatty acids, C18-unsatd., dimers, polymers with ethylenediamine, hexamethylenediamine, and propionic acid 67989-30-4	Low concern overall.	

Chemical name and CAS number	Summary of SAT report and available acute data	Reference
1-Hydroxycyclohexyl phenyl ketone 947-19-3	Low concern overall.	
Hydroxylamine derivative NK	Moderate concern for genotoxicity, dermal sensitization, and developmental toxicity.	
Isopropoxyethoxytitanium bis(acetylacetonate) 68586-02-7	Moderate concern for neurotoxicity, genotoxicity, oncogenicity, and developmental/reproductive toxicity. This material is expected to be reactive, which may result in irritation of the eyes, skin, and mucous membranes.	
2-Isopropylthioxanthone 5495-84-1	Low concern overall.	
4-Isopropylthioxanthone 83846-86-0	Low concern overall.	
2-Methoxy-1-propanol	Low to Moderate concern for developmental toxicity, neurotoxicity, and immunosuppression.	
Methylenedisalicylic acid 27496-82-8	Low to Moderate concern for effects on blood clotting, sensitization, immunosuppression, irritation of mucous membranes, developmental toxicity, endocrine disruption, and genotoxicity.	
Nitrocellulose 9004-70-0	Oral LD <sub>50</sub> in rats and mice > 5 grams/kg. Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. Low concern for other effects.	15
Paraffin wax 8002-74-2	Low to Moderate concern for respiratory effects.	
Polyethylene 9002-88-4	IARC (1987) has classified polyethylene as a Group 3 compound, not classifiable as to its carcinogenicity to humans, based on no adequate evidence in humans and inadequate evidence in experimental animals. Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. Low concern for other effects.	57
Polyol derivative A —	Low concern overall.	
Resin acids, hydrogenated, methyl esters 8050-15-5	Low concern overall. There is uncertain concern for respiratory sensitization.	
Rosin, fumarated, polymer with diethylene glycol and pentaerythritol 68152-50-1	Low concern overall unless respirable particles of high molecular weight species (>10,000) are inhaled. There is uncertain concern for respiratory sensitization. Low concern for other effects.	
Rosin, fumarated NK	Low concern overall.	
Rosin, polymerized 65997-05-9	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. There is uncertain concern for respiratory sensitization. Low concern for other effects.	
Silamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica 68909-20-6	Low to Moderate concern for lung effects (silicosis) if crystalline material is inhaled. Low concern for other effects.	

Table 3-B.2 SAT Reports and Available Acute Data for Chemicals with No or Inadequate Hazard Data (continued)

Chemical name and CAS number	Summary of SAT report and available acute data	Reference
Siloxanes and silicones, di-Me, 3-hydroxypropyl Me, ethers with polyethylene glycol acetate 70914-12-4	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. Low concern for other effects.	
Solvent naphtha (petroleum), light aliphatic 64742-89-8	Low to Moderate concern for neurotoxicity and lung irritation. The material may also cause defatting of the skin through prolonged exposure.	
Styrene acrylic acid polymer #1 NK	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. Low concern for other effects.	
Styrene acrylic acid polymer #2 NK	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. Low concern for other effects.	
Styrene acrylic acid resin NK	Low to Moderate concern for lung effects if respirable particles of high molecular weight species (>10,000) are inhaled. Low concern for other effects.	
Tetramethyldecyndiol 126-86-3	Low concern for eye, skin, lung, and mucous membrane irritation, and neurotoxic, liver, and kidney effects.	
Thioxanthone derivative NK	Low to Moderate concern for neurotoxicity.	
Titanium diisopropoxide bis(2,4-pentanedionate) 17927-72-9	This material is expected to be reactive, which may result in irritation of the eyes, skin, and mucous membranes. Moderate concern based on release of hydrolysis products: 2,4 pentanedione, inorganic titanium, and isopropanol. 2,4 pentanedione: concern for neurotoxicity, mutagenicity, oncogenicity, and developmental/reproductive toxicity. Inorganic titanium: concern for mutagenicity and oncogenicity. Isopropanol: concern for liver, neurotoxic, reproductive, respiratory, and spleen effects; changes in enzyme levels and clinical and urine chemistry; fetal death, musculoskeletal abnormalities, fetotoxicity, blood and skin effects, tissue necrosis at application site, increased kidney and liver weight.	
Titanium isopropoxide 546-68-9	This material is expected to be reactive, which results in moderate concern for irritation of the eyes, skin, and mucous membranes. Moderate concern based on release of the hydrolysis products, inorganic titanium and isopropanol. Inorganic titanium: concern for mutagenicity and oncogenicity. Isopropanol: concern for liver, neurotoxic, reproductive, respiratory, and spleen effects; changes in enzyme levels and clinical and urine chemistry; fetal death, musculoskeletal abnormalities, fetotoxicity, blood and skin effects, tissue necrosis at application site, increased kidney and liver weight.	
Trimethylolpropane propoxylate triacrylate 53879-54-2	Low to Moderate concern for oncogenicity, mutagenicity, developmental and reproductive effects, sensitization, and irritation.	

<sup>a</sup> SAT reports are generated by the OPPT Structure-Activity Team to predict toxicity based on analog data and/or structure-activity considerations.

## REFERENCES FOR TABLES 3-B.1 AND 3-B.2

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## ENVIRONMENTAL HAZARD ASSESSMENT METHODOLOGY

### *Hazard Profile*

The environmental hazard assessment of chemicals consists of the identification of the effects that a chemical may have on organisms in the environment. An overview of this assessment process has been reported, for example, by Smrchek and Zeeman (1998)<sup>1</sup> and by Zeeman and Gilford (1993a)<sup>2</sup>. The effects are expressed in terms of the acute and chronic toxicity of a chemical on the exposed organisms. There are generally given as either the lethal concentration (LC) or as the effective concentration (EC), which describe the type and seriousness of the effect for a known concentration of a chemical. When the effective concentrations for a range of species for a chemical are tabulated, the tabulation is called a Hazard Profile or Toxicity Profile. A more detailed discussion of a comprehensive Hazard Profile has been presented by Nabholz, 1991.<sup>3</sup> The most frequently used Hazard Profile for the aquatic environment consists of a set of six effective concentrations as reported by Nabholz, et al., (1993a).<sup>4</sup> These are:

- Fish acute value (usually a fish 96-hour LC<sub>50</sub> value)
- Aquatic invertebrate acute value (usually a daphnid 48-hour LC<sub>50</sub> value)
- Green algal toxicity value (usually an algal 96-hour EC<sub>50</sub> value)
- Fish chronic value [usually a fish 28-day chronic value (ChV)]
- Aquatic invertebrate chronic value (usually a daphnid 21-day ChV)
- Algal chronic value [usually an algal 96-hour no effect concentration (NEC) or geometric mean maximum acceptable toxicant concentration (GMATC) value for biomass]

For the acute values, the LC<sub>50</sub> (lethality or mortality) or EC<sub>50</sub> (non-lethal effects) refers to the concentration that results in 50 percent of the test organisms affected at the end of the specified exposure period in a toxicity test. The chronic values represent the concentration of the chemical that results in no statistically significant sublethal effects on the test organism following an extended or chronic exposure.

The Hazard Profile can be constructed using effective concentrations based on toxicity test data (with measured test chemical concentrations) or estimated toxicity values based on Structure Activity Relationships (SARs). The measured values are preferred because they are based on actual test data, but SAR estimates, if available for the chemical class, can be used in the absence of test data. Thus the Hazard Profile may consist of only measured data, only predicted values, or a combination of both. Also, the amount of data in the hazard profile may range from a minimum of one acute or chronic value to the full compliment of three acute values and three chronic values.

In the absence of measured toxicity values, estimates of these values can be made using Structure Activity Relationships (SARs). SAR methods include Quantitative Structure Activity Relationships (QSARs), qualitative SARs or the use of the chemical analogs. The

use of SARs by OPPT has been described in other texts.<sup>5</sup> The use and application of QSARs specifically for the hazard assessment of new TSCA chemicals has been presented in other information sources as well.<sup>6</sup> The development, validation and application of SARs in OPPT have been presented by OPPT staff.<sup>7,8,9,10,11,12</sup>

The predictive equations (QSARs) are used in lieu of actual test data to estimate a toxicity value for aquatic organisms within a specific chemical class. The chemical classes and subclasses with available QSARs, numbering a total of 140, have been listed.<sup>13,14</sup> Although the equations are derived from correlation and linear regression analysis based on measured data, the confidence intervals associated with the equation are not used to provide a range of toxicity values. Even with measured test data, the use of the confidence limits to determine the range of values is not used.

#### ***Determination of Concern Concentration***

Upon completion of a hazard profile, a concern concentration (CC) is determined. A concern concentration is that concentration of a chemical in the aquatic environment which, if exceeded, may cause a significant risk to aquatic organisms. Conversely, if the CC is not exceeded, the assumption is made that probability of a significant risk occurring is low and no regulatory action is required. The CC for each chemical is determined by applying Assessment Factors (AsF)<sup>15</sup> or Uncertainty Factors (UF)<sup>16</sup> to the effect concentrations in the hazard profile.

These factors incorporate the concept of the uncertainty associated with (1) toxicity data; laboratory tests versus field test and measured versus estimated data and (2) species sensitivity. For example, if only a single LC<sub>50</sub> value for a single species, is available, there are several uncertainties to consider. First, how reliable is the value itself? If the test were to be done again by the same laboratory or a different laboratory, would the value differ, and if so, by how much? Second, there are differences in sensitivity (toxicity) among and between species that have to be considered. Is the species tested the most or the least sensitive? In general, if only a single toxicity value is available, there is a large uncertainty about the applicability of this value to other organisms in the environment and large assessment factor, i.e., 1000, is applied to cover the breadth of sensitivity known to exist among and between organisms in the environment. Conversely, the more information that is available results in more certainty concerning the toxicity values and requires the use of smaller factors. For example, if toxicity values are derived from field tests, then an assessment factor on 1 is used, because these tools measure chemical effects on field organisms.

Four factors are used by OPPT to set a CC for chronic risk: 1, 10, 100, and 1000. The factor used is dependent on the amount and type of toxicity data contained in the hazard profile and reflects the amount of uncertainty about the potential effects associated with a toxicity value. In general, the more complete the hazard profile and the higher the quality of the generated toxicity data, the smaller the factor that is used. The following discussion describes the use and application of the uncertainty or assessment factors:

- If the hazard profile only contains one or two acute toxicity values, the concern concentration is set at 1/1000 of the acute value.

- If the hazard profile contains three acute values (called the base set), the concern concentration is set at 1/100 of the lowest acute value.
- If the hazard profile contains one chronic value, the concern concentration is set at 1/10 of the chronic value if the value is for the most sensitive species. Otherwise, it is 1/100 of the acute value for the most sensitive species.
- If the hazard profile contains three chronic values, the concern concentration is set at 1/10 of the lowest chronic value.
- If the hazard profile contains a measured chronic value from a field study, then an assessment factor of 1 is used.

### ***Hazard Ranking***

Chemicals can also be ranked by their hazard concern levels for the aquatic environment. This ranking can be based upon the acute toxicity values expressed in milligrams per liter (mg/L). The generally accepted scoring used by OPPT is as follows:<sup>17,18</sup>

High Concern (H)	≤ 1
Moderate (or Medium) Concern (M)	> 1 and ≤ 100
Low Concern (L)	> 100

This ranking can also be expressed in terms of chronic values as follows:

High Concern (H)	≤ 0.1
Moderate (or Medium) Concern (M)	> 0.1 and ≤ 10.0
Low Concern (L)	> 10.0

Chronic toxicity ranking takes precedent over the acute ranking.

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**Table 3-B.3 Estimated Lowest Aquatic Toxicity Values of Flexographic Ink Chemicals Based on SAR Analysis or on Actual Measured Test Data**

Chemical	Acute toxicity (mg/L)			Chronic toxicity (mg/L)			Concern concen- tration
	Fish	Invert.	Algal	Fish	Invert.	Algal	
Acrylated epoxy polymer	a						
Acrylated oligoamine polymer	a						
Acrylated polyester polymer #1	a						
Acrylated polyester polymer #2	a						
Acrylic acid-butyl acrylate-methyl methacrylate-styrene polymer	a						
Acrylic acid polymer, acidic #1	≥300	≥400	9	≥30	≥40	1	>1
Acrylic acid polymer, acidic #2	≥300	≥400	9	≥30	≥40	1	>1
Acrylic acid polymer, insoluble	a						
Alcohols, C11-15-secondary, ethoxylated	1	1	1	0.2	0.2	0.3	0.02
Amides, tallow, hydrogenated	b	b	b	0.002	0.005	0.01	0.001
Ammonia fresh water	0.93	1.91	2.4	0.07	0.6	0.6	0.01-0.006
salt water	1.1	1.0		0.06	0.14		
Ammonium hydroxide	12	32	>30	1	3	>3	0.3
Barium	580	24	31	23	13	7.7	0.8
2-Benzyl-2-(dimethylamino)-4'-morpholinobutyrophenone	2.0	1	1.5	0.3	0.2	0.6	0.02
Butyl acetate	25	170	2	3	7.8	1.5	0.2
Butyl acrylate-methacrylic acid-methyl methacrylate polymer	a						
Butyl carbitol fresh water	1300	1300	760	140	41	40	2-4
salt water	170	821					
C.I. Basic Violet 1, molybdatephosphate	0.05 or <sup>a</sup>	0.05 or <sup>a</sup>	0.05 or <sup>a</sup>	0.05 or <sup>a</sup>	0.005 or <sup>a</sup>	0.01 or <sup>a</sup>	0.001
C.I. Basic Violet 1, molybdate tungstatephosphate	0.08 or <sup>a</sup>	0.05 or <sup>a</sup>	0.04 or <sup>a</sup>	0.008 or <sup>a</sup>	0.005 or <sup>a</sup>	0.01 or <sup>a</sup>	0.001 for solub. ≥0.005
C.I. Pigment Blue 15	a						
C.I. Pigment Blue 61	≤70	≤70	≤10	≤7	≤7	≤1	0.1
C.I. Pigment Green 7	a						
C.I. Pigment Red 23	a						
C.I. Pigment Red 48, barium salt (1:1)	≥30	≥30	20	≥3	≥3	2	0.3
C.I. Pigment Red 48, calcium salt (1:1)	≥30	≥30	20	≥3	≥3	2	0.3
C.I. Pigment Red 52, calcium salt (1:1)	30	40	170	3	3	≥20	0.3
C.I. Pigment Red 269	a						
C.I. Pigment Violet 23	a						
C.I. Pigment Violet 27	0.05 or <sup>a</sup>	0.05 or <sup>a</sup>	0.05 or <sup>a</sup>	0.005 or <sup>a</sup>	0.005 or <sup>a</sup>	0.005 or <sup>a</sup>	0.001
C.I. Pigment White 6	a						
C.I. Pigment White 7	a						

Chemical	Acute toxicity (mg/L)			Chronic toxicity (mg/L)			Concern concentration
	Fish	Invert.	Algal	Fish	Invert.	Algal	
C.I. Pigment Yellow 14	a						
C.I. Pigment Yellow 74	a						
Citric acid in hard water	>100	>100	5 100	10	10	1 30	0.1 3.0

**Table 3-B.3 Estimated Lowest Aquatic Toxicity Values of Flexographic Ink Chemicals Based on SAR Analysis or on Actual Measured Test Data (continued)**

Chemical	Acute toxicity (mg/L)			Chronic toxicity (mg/L)			Concern concentration
	Fish	Invert.	Algal	Fish	Invert.	Algal	
D&C Red No. 7	29	37	20	>3	2.6	2	0.2-0.3
Dicyclohexyl phthalate	b	b	0.05	0.03	0.03	0.04	0.003
Diethyl sulfosuccinate, sodium salt	3	3	30	0.5	.05	3	0.05
Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide	3	5.2	0.43	0.4	0.61	0.35	0.04
Dipropylene glycol diacrylate	3.8	26	2.7	0.25	3	6	0.03
Dipropylene glycol methyl ether	5000	4600	2600	500	110	95	10
Distillates (petroleum), hydrotreated light	0.23	0.3	0.22	0.05	0.05	0.1	0.005
Distillates (petroleum), solvent-refined light paraffinic	a						
Erucamide	a						
Ethanol	4300	4000	6100	390	76	60	6
Ethanolamine	1035	100	63	200	10	0.85	0.09
Ethoxylated tetramethyldecynidiol	>50	>50	>50	>10	>10	>10	1
Ethyl acetate	66	>1000	5	7	>100	3.7	0.4
Ethyl carbitol	>1000	>1000	>1000	900	190	150	20
Ethyl 4-dimethylaminobenzoate	13	15	10	2	1.3	1.9	0.1
2-Ethylhexyl diphenyl phosphate	b	b	0.05	0.03	0.03	0.04	0.003
Fatty acid, dimer-based polyamide	a						
Fatty acids, C18-unsatd., dimers, polymers with ethylenediamine, hexamethylenediamine, and propionic acid	a						
Glycerol propoxylate triacrylate	≤4.5	≤14	≤1.6	≤0.13	≤0.1	≤0.4	0.01
n-Heptane	0.41	0.52	0.37	0.08	0.08	0.15	0.008
1,6-Hexanediol diacrylate	2.4	7.6	0.82	0.2	0.8	0.07	0.007
1-Hydroxycyclohexyl phenyl ketone	33	37	24	4.8	2.6	3.6	0.3
Hydroxylamine derivative	≤54	≤3.9	≤6.8	≤5	≤0.4	≤1.4	0.04
2-Hydroxy-2-methylpropiophenone	450	460	280	52	18	20	2
Hydroxypropyl acrylate	4.9	160	15	1.7	20	4	0.2
Isobutanol	930	910	530	97	26	25	2.5
Isopropanol	2700	2600	1400	260	57	48	5
Isopropoxyethoxytitanium bis(acetylacetonate)	13	15	10	2	1.4	2.3	0.1, ≥1.0 <sup>c</sup>
2-Isopropylthioxanthone	b	b	b	0.004	0.004	0.004	0.001

**Table 3-B.3 Estimated Lowest Aquatic Toxicity Values of Flexographic Ink Chemicals Based on SAR Analysis or on Actual Measured Test Data (continued)**

Chemical	Acute toxicity (mg/L)			Chronic toxicity (mg/L)			Concern concentration
	Fish	Invert.	Algal	Fish	Invert.	Algal	
4-Isopropylthioxanthone	b	b	b	0.03 or <sup>a</sup>	0.03 or <sup>a</sup>	0.03 or <sup>a</sup>	0.003
Kaolin	>1000	>1000	>1000	>100	50	>100	5.0
Methylenedisalicylic acid	>100	>100	30	>10	>10	3	0.3
2-Methyl-4'-(methylthio)-2-morpholinopropiophenone	45	51	33	6.6	3.6	5	0.4
Mineral oil	b	b	b	0.002 or <sup>a</sup>	0.004 or <sup>a</sup>	0.010 or <sup>a</sup>	0.001
Nitrocellulose	>100	>100	>100	>10	>10	>10	1
Paraffin wax	a						
Phosphine oxide, bis(2,6-dimethoxybenzoyl) (2,4,4-trimethylpentyl)-	5.1 or <sup>a</sup>	5.1 or <sup>a</sup>	0.78 or <sup>a</sup>	0.9 or <sup>a</sup>	1.2 or <sup>a</sup>	0.62 or <sup>a</sup>	0.06
Polyethylene glycol	>100	>100	>100	>10	>10	>10	1
Polyol derivative A	>1000	>1000	>1000	>100	>100	>100	10
Polytetrafluoroethylene	a						
Propanol	1800	1700	970	180	42	36	4
Propyl acetate	41	430	3.2	4	16	2.4	0.2
Propylene glycol methyl ether	>1000	>1000	>1000	>1000	210	160	20
Propylene glycol propyl ether	≥1000	≥1000	≥980	≥180	≥47	≥44	4
Resin acids, hydrogenated, methyl esters	b	b	b	0.001 or <sup>a</sup>	0.001 or <sup>a</sup>	0.005 or <sup>a</sup>	0.001
Resin, acrylic	≥300	≥400	9	≥30	≥40	1	>1
Rosin, fumarated, polymer with diethylene glycol and pentaerythritol	a						
Rosin, fumarated, polymer with pentaerythritol, 2-propenoic acid, ethenylbenzene, and (1-methylethylenyl)benzene	a						
Rosin, polymerized	a						
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	>100 or <sup>a</sup>	>100 or <sup>a</sup>	>100 or <sup>a</sup>	>10 or <sup>a</sup>	>10 or <sup>a</sup>	>10 or <sup>a</sup>	>1 or <sup>a</sup>
Silica	a						
Silicone oil	>100 or <sup>a</sup>	>100 or <sup>a</sup>	>100 or <sup>a</sup>	>10 or <sup>a</sup>	>10 or <sup>a</sup>	>10 or <sup>a</sup>	1.0 or <sup>a</sup>
Siloxanes and silicones, di-Me, 3-hydroxypropyl Me, ethers with polyethylene glycol acetate	>100	>100	>100	>10	>10	>10	>1
Solvent naphtha (petroleum), light aliphatic	1.8	2.2	1.5	0.31	0.23	0.38	0.02
Styrene	4	13	0.72	1.6	0.95	0.06	0.006
Styrene acrylic acid polymer #1	≥300	≥400	9	≥30	≥40	1	>1
Styrene acrylic acid polymer #2	≥300	≥400	9	≥30	≥40	1	>1
Styrene acrylic acid resin	≥300	≥400	9	≥30	≥40	1	>1
Tetramethyldecyldiol	31	30	30	3	3	3	0.3
Thioxanthone derivative	b	b	b	0.05 or <sup>a</sup>	0.05 or <sup>a</sup>	0.05 or <sup>a</sup>	0.005

**Table 3-B.3 Estimated Lowest Aquatic Toxicity Values of Flexographic Ink Chemicals Based on SAR Analysis or on Actual Measured Test Data (continued)**

Chemical	Acute toxicity (mg/L)			Chronic toxicity (mg/L)			Concern concentration
	Fish	Invert.	Algal	Fish	Invert.	Algal	
Titanium diisopropoxide bis (2,4-pentanedionate)	≥220	≥110	≥19	≥20	≥10	≥5	0.5
Titanium isopropoxide	≥2900	≥2700	≥1500	≥270	≥60	≥50	5
Trimethylolpropane ethoxylate triacrylate	≥8	≥70	≥7	≥0.6	≥7	≥2	0.06
Trimethylolpropane propoxylate triacrylate	≤5.5	≤22	≤2.4	≤0.21	≤2	≤0.6	0.02
Trimethylolpropane triacrylate	4.1	23.0	2.4	0.21	2	0.6	0.02
Urea	> 1000	> 1000	> 1000	> 100	> 100	> 100	> 10

<sup>a</sup> No effects are expected because the chemical is a polymer or a high-molecular weight compound. The high molecular weight (greater than 600 or 1,000) prevents passage through biological membranes.

<sup>b</sup> No toxic effects are expected in a saturated solution during the prescribed test duration, or no toxic effects can be measured due to low water solubility.

<sup>c</sup> The first value (0.1) pertains to the stable complex of this chemical, and the second value (>1.0) pertains to the hydrolysis products.

Table 3-B.4 Environmental Hazard Ranking of Flexographic Ink Chemicals

Chemical	CAS number	Lowest chronic value (mg/L)	Hazard rank <sup>a</sup>
Acrylated epoxy polymer		<sup>b</sup>	L
Acrylated oligoamine polymer		<sup>b</sup>	L
Acrylated polyester polymer #1		<sup>b</sup>	L
Acrylated polyester polymer #2		<sup>b</sup>	L
Acrylic acid-butyl acrylate-methyl methacrylate-styrene polymer	27306-39-4	<sup>b</sup>	L
Acrylic acid polymer, acidic #1		1	M
Acrylic acid polymer, acidic #2		1	M
Acrylic acid polymer, insoluble		<sup>b</sup>	L
Alcohols, C11-15-secondary, ethoxylated	68131-40-8	0.2	M
Amides, tallow, hydrogenated	61790-31-6	0.002	H
Ammonia	7664-41-7	0.06	H
Ammonium hydroxide	1336-21-6	1	M
Barium	7440-39-3	7.7	L
2-Benzyl-2-(dimethylamino)-4'-morpholinobutyrophenone	119313-12-1	0.2	M
Butyl acetate	123-86-4	1.5	M
Butyl acrylate-methacrylic acid-methyl methacrylate polymer	25035-69-2	<sup>b</sup>	L
Butyl carbitol	112-34-5	40	L
C.I. Basic Violet 1, molybdatephosphate	67989-22-4	0.005	H
C.I. Basic Violet 1, molybdatetungstatephosphate	1325-82-2	0.005	H
C.I. Pigment Blue 15	147-14-8	<sup>b</sup>	L
C.I. Pigment Blue 61	1324-76-1	≤ 1	M
C.I. Pigment Green 7	1328-53-6	<sup>b</sup>	L
C.I. Pigment Red 23	6471-49-4	<sup>b</sup>	L
C.I. Pigment Red 48, barium salt (1:1)	7585-41-3	2	M
C.I. Pigment Red 48, calcium salt (1:1)	7023-61-2	2	M
C.I. Pigment Red 52, calcium salt (1:1)	17852-99-2	3	M
C.I. Pigment Red 269	67990-05-0	<sup>b</sup>	L
C.I. Pigment Violet 23	6358-30-1	<sup>b</sup>	L
C.I. Pigment Violet 27	12237-62-6	0.005	H
C.I. Pigment White 6	13463-67-7	<sup>b</sup>	L
C.I. Pigment White 7	1314-98-3	<sup>b</sup>	L
C.I. Pigment Yellow 14	5468-75-7	<sup>b</sup>	L
C.I. Pigment Yellow 74	6358-31-2	<sup>b</sup>	L

Chemical	CAS number	Lowest chronic value (mg/L)	Hazard rank <sup>a</sup>
Citric acid	77-92-9	1	M
D&C Red No.7	5281-04-9	2	M
Dicyclohexyl phthalate	84-61-7	0.03	H

Table 3-B.4 Environmental Hazard Ranking of Flexographic Ink Chemicals (continued)

Chemical	CAS number	Lowest chronic value (mg/L)	Hazard rank <sup>a</sup>
Diethyl sulfosuccinate, sodium salt	577-11-7	0.5	M
Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide	75980-60-8	0.35	M
Dipropylene glycol diacrylate	57472-68-1	0.25	M
Dipropylene glycol methyl ether	34590-94-8	95	L
Distillates (petroleum), hydrotreated light	64742-47-8	0.05	H
Distillates (petroleum), solvent-refined light paraffinic	64741-89-5	<sup>b</sup>	L
Erucamide	112-84-5	<sup>b</sup>	L
Ethanol	64-17-5	60	L
Ethanolamine	141-43-5	0.85	M
Ethoxylated tetramethyldecyldiol	9014-85-1	> 10	L
Ethyl acetate	141-78-6	3.7	M
Ethyl carbitol	111-90-0	150	L
Ethyl 4-dimethylaminobenzoate	10287-53-3	1.3	M
2-Ethylhexyl diphenyl phosphate	1241-94-7	0.03	H
Fatty acid, dimer-based polyamide		<sup>b</sup>	L
Fatty acids, C18-unsatd., dimers, polymers with ethylenediamine, hexamethylenediamine, and propionic acid	67989-30-4	<sup>b</sup>	L
Glycerol propoxylate triacrylate	52408-84-1	≤ 0.13	H
n-Heptane	142-82-5	0.08	H
1,6-Hexanediol diacrylate	13048-33-4	0.07	H
1-Hydroxycyclohexyl phenyl ketone	947-19-3	2.6	M
Hydroxylamine derivative		0.4	M
2-Hydroxy-2-methylpropiophenone	7473-98-5	18	L
Hydroxypropyl acrylate	25584-83-2	1.7	M
Isobutanol	78-83-1	25	L
Isopropanol	67-63-0	48	L
Isopropoxyethoxytitanium bis(acetylacetonate)	6858-02-7	4.6	M
2-Isopropylthioxanthone	5495-84-1	0.004	H



Table 3-B.4 Environmental Hazard Ranking of Flexographic Ink Chemicals (continued)

Chemical	CAS number	Lowest chronic value (mg/L)	Hazard rank <sup>a</sup>
4-Isopropylthioxanthone	83846-86-0	0.03	H
Kaolin	1332-58-7	50	L
Methylenedisalicylic acid	27496-82-8	3	M
2-Methyl-4'(methylthio)-2-morpholinopropiophenone	71868-10-5	3.6	M
Mineral oil	8012-95-1	0.002	H
Nitrocellulose	9004-70-0	> 10	L
Paraffin wax	8002-74-2	<sup>b</sup>	L
Phosphine oxide, bis(2,6-dimethoxybenzoyl) (2,4,4-trimethylpentyl)-	145052-34-2	0.6	M
Polyethylene	9002-88-4	<sup>b</sup>	L
Polyethylene glycol	25322-68-3	> 10	L
Polyol derivative A		> 100	L
Polytetrafluoroethylene	9002-84-0	<sup>b</sup>	L
Propanol	71-23-8	36	L
Propyl acetate	109-60-4	2.4	M
Propylene glycol methyl ether	107-98-2	160	L
Propylene glycol propyl ether	1569-01-3	≥ 44	L
Resin acids, hydrogenated, methyl esters	8050-15-5	0.001	H
Resin, acrylic	29003-01-4	1	M
Rosin, fumarated, polymer with diethylene glycol and pentaerythritol	68152-50-1	<sup>b</sup>	L
Rosin, fumarated, polymer with pentaerythritol, 2-propenoic acid, ethenylbenzene, and (1-methylethenyl)benzene		<sup>b</sup>	L
Rosin, polymerized	65997-05-9	<sup>b</sup>	L
Silamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	68909-20-6	>10	L
Silica	7631-86-9	<sup>b</sup>	L
Silicone oil	63148-62-9	> 10	L
Siloxanes and silicones, di-Me, 3-hydroxypropyl Me, ethers with polyethylene glycol acetate	70914-12-4	> 10	L
Solvent naphtha (petroleum), light aliphatic	64742-89-8	0.23	M
Styrene	100-42-5	0.06	H
Styrene acrylic acid polymer #1	25005-34-1	1	M
Styrene acrylic acid polymer #2		1	M
Styrene acrylic acid resin		1	M
Tetramethyldecyldiol	126-86-3	3	M

Table 3-B.4 Environmental Hazard Ranking of Flexographic Ink Chemicals (continued)

Chemical	CAS number	Lowest chronic value (mg/L)	Hazard rank <sup>a</sup>
Thioxanthone derivative		0.05	H
Titanium diisopropoxide bis (2,4-pentanedionate)	17927-72-9	5	M
Titanium isopropoxide	546-68-9	50	L
Trimethylolpropane ethoxylate triacrylate	28961-43-5	$\geq 0.06$	H
Trimethylolpropane propoxylate triacrylate	53879-54-2	$\leq 0.21$	M
Trimethylolpropane triacrylate	15625-89-5	0.21	M
Urea	57-13-6	> 100	L

<sup>a</sup> Ranking based on the lowest estimated chronic value; H = high, M = medium, L = low.

<sup>b</sup> No effects are expected because the chemical is a polymer or a high-molecular weight compound. The high molecular weight (greater than 600 or 1000) prevents passage through biological membranes.